This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

OIPE JC26
OCT 21 2003
PATENT & TRADEMARK OFFICE

Attorney's Docket No:cardiobeat-2
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	:	
George McBride, et al	:	
Filed: 03/27/2000	:	EXAMINER: PAUL L. KIM
Title: Medical Testing Internet Server System and Method	:	Art Unit 2857
Serial No.: 09/535,185	:	
	:	

DECLARATION UNDER 37 C.F.R. 1.131
By
GEORGE MCBRIDE

I, GEORGE MCBRIDE hereby declare as follows:

1. My address is 4519 East Peakview, Cave Creek, AZ 85331

2. On or prior to July 9, 1999, Robert Royce and I conceived the invention that is the subject of the above-identified patent application. Evidence of this conception is an emailed executive summary of the project dated July 09, 1999, a redacted copy of which is attached hereto as Exhibit 1.

3. Subsequent to the conception of the invention Robert Royce and I were diligent in reducing the invention to practice as evidenced by a continuous development activity pertaining to the reduction to practice of the invention. Subsequent to July 9, 1999, a new corporate entity was formed, Cardiobeat.com, to develop and market the invention. I prepared several draft development plans for the invention, one version of which was sent by email to Robert Royce and Larry MacDonald and which is attached hereto as Exhibit 2.

4. During the time that I was preparing the development plan, I and/or Robert Royce consulted with contract engineering firms relative to having assistance in reducing various aspects of the invention to practice. One such communications was an email from Warren Williamson dated August 17, 1999 that was forwarded to me by Robert Royce proposing design approaches to implementations of the invention. A copy of the email is attached as Exhibit 3.

5. From at least as early as August 17, 2002, Robert Royce worked substantially continuously and diligently at reducing the invention to practice as an employee and owner of Cardiobeat.com, assignee of the subject invention.

6. At frequent times throughout the development activity of the invention, we consulted with Dr. James Buell, regarding medical applications and impedance cardiography, which is used

10/20/2003 10:02 FAX 480 419 3966 CB Fax1 001

in the illustrative embodiment of the invention. One email communication that I received from Dr. Buell is attached hereto as Exhibit 4 dated 9/18/1999.

7. At all times subsequent to the conception of the invention, both Robert Royce and I continued to work on the reduction to practice of the invention including development of software. A portion of a business plan that I authored is attached as Exhibit 5, dated October 1, 1999, and describes a software program that was developed as part of this ongoing activity.

8. Robert Royce provided a status report to me by email dated October 15, 1999, attached as Exhibit 6, that discusses the development of aspects of the invention and includes an attached flow chart. The flow chart indicates that a portion of the database activity that is part of the reduction to practice of the invention is "about ½ done at this time". The database activity was performed prior to October 15, 2002.

9. Development activity continued without interruption subsequent to the status report of October 15, 1999. On December 22, 1999, a meeting was held to review the development status of the invention. A copy of the overview of that development status is attached as Exhibit 7.

10. From December 23, 1999 through March 27, 2000, I along with Robert Royce had several meetings with Donald J. Lenkszus to disclose our invention and the illustrative embodiment development with him so that he could prepare and file patent applications on the subject invention and related inventions.

11. Warren Williamson of W.L. Williamson & Associates provided engineering services throughout this stage of the development activities up to and beyond the filing date of the subject patent application. Mr. Williamson provided engineering service at our direction to provide an implementation of the invention.

12. All the attached documents are true copies of original documents.

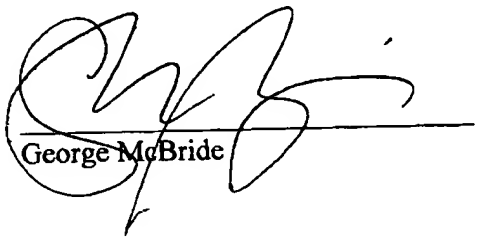
13. Throughout the period from conception of the invention through the filing date of the above-identified patent application, Robert Royce and I continuously and diligently worked on reducing the invention to practice either through our direct personal efforts and/or through direction of others in implementing various aspects of the product embodying the invention.

I
I
I
I
I
I

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements

10/20/2003 10:02 FAX 480 419 3966 CB Fax1 002

were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



George McBride

Date: OCTOBER 20, 2003

10/20/2003 10:03 FAX 480 419 3966 CB FaxI 003

EXHIBIT 1

GMcBrid /cardi b at.com

From: George McBride
Sent: Friday, July 09, 1999 13:27
T : 'bob@softque.com'
Subject: FW: Executive Summary - Cardiac Technology Business Plan

Bob,

The following Executive Summary was sent to Mike Buchanan for his comments. Larry and I would like your reaction and comments as a "fresh" reader. When you work on a document extensively the substance becomes familiar and objectivity is lost. Any comments to improve clarity would be appreciated.

The purpose of the summary is to sell the idea and convey the scope. Details (how this will happen) will be integrated into the business plan. We expect that you will be frustrated by the broad sweep of the summary. Even with that, will it sell the concept?

George McBride
Asset Technologies, Inc.
Direct Phone: 602-418-0464
Office: 480-998-8900
Fax: 480-922-0500
Email: gmcbride@assettech.com
Web Page: www.assettech.com

-----Original Message-----
From: **George McBride**
Sent: July 09, 1999 13:18
To: J. Michael Buchanan (E-mail)
Cc: Larry Macdonald (E-mail)
Subject: Executive Summary - Cardiac Technology Business Plan

Mike,

Please comment on this executive summary. Does it tell the story?
Lets talk about how to proceed and how quickly we can move. The funding requirement is based on having a product available in 6 months with full deployment in a year.

Thanks again for the hospitality.

Draft Executive Summary.

CONFIDENTIAL, DO NOT COPY...

DiagnosticDoctor.com

Executive Summary

About Cardiac Technology

Cardiac Technology (CT) has developed and is selling non-invasive diagnostic systems. The first product is Hemodynamic Monitoring (HD) a procedure that replaces invasive heart catheterization providing information on strok volume, cardiac output, systemic resistance, and cardiac function indices.
The Portable Cardiac Lab (PCL), the current product, is sold to hospitals, private physicians, and emergency technicians to obtain patient cardiovascular information utilizing a noninvasive procedure at very low cost.
The proprietary software that performs HD is the most advanced analytical software of its kind.

Market Opp rtunity

58 million Americans afflicted with heart disease spend $259 billion each year on treatment. The international market is over twice the size of the US. Ever increasing medical care costs demand cost effective treatment programs like HD. The incidence of heart disease increases as life expectancy increases, such as, congestiv heart failure and strok s. Hemodynamic parameters are critical in assessing cardiac function. Yet these parameters are currently difficulty and expensive to obtain. Currently the preferred method of obtaining this information is invasive catheterization, which is expensive and life threatening.
HD can be sold to the consumer through an Internet implementation at a greatly reduced cost. The testing logic will be downloaded for each test. The data collection sensors can be connected into any PC with a serial port (or USB). HD software will be downloaded for each test on a fee basis. Test results will be stored in a database for use by physicians and others. The cost of the sensors can be reduced to le[redacted]or the consumer market. Pricing a single HD procedure at[redacted]versus $[redacted]for a catheterization will expand the market to anyone in need.
HD will establish a channel for distribution of other tests and procedures, such as, stress and blood pressure tests.
The FDA has approved HD for Cardio Dynamics, a competitor, along with Medicare reimbursement qualification. CT has not submitted an application for approval. Based on the Cardio Dynamics approval, CT expects that approval, when requested, will be forthcoming.

Testing over the Internet

As the cost of health care rises individuals are taking a greater role in their medical care for both preventive and remedial medicine. HD offers direct access to a key cardiovascular test for a small cost. Home testing is testing on demand for those with heart disease that require regular monitoring. Immediate access to key tests and equally rapid transfer of the results to the care group will become an essential part of quality treatment in the future.
Establishing this channel will provide for distributing other medical and health products. HD will be the first of many procedures sold over the Internet. Establishing this test will position the Cardiac Technology as a primary channel for medical care through the Internet.

Time to market

Rapid deployment is critical to dominating the market. The HD technology is state of art, tested, and complete. The Internet deployment capability must be completed for general deployment. CT plans to begin field-testing several hundred users in three months with larger tests in six months. Broad deployment would begin in 12 months.

Pricing and Revenue

The average cost per test is[redacted]If each of the 60 million Americans afflicted with heart disease used HD once each year, the revenues would be $4.1 billion. CT expects HD will be used address a broad range of cardiac concerns from health interest to intensive care.
The channel developed for distributing HD can be used for advertising and distribution of related products and services.

Funding & Financial Summary

Need for Funding

CT is seeking $[redacted]in funding to deliver the PCL Test through the Internet.
Funding is required to

- develop the Internet delivery system,
- upgrade the diagnostic code,
- construct the administrative and customer management systems,
- build the database to hold the test data, and
- reduce the cost of the sensors.

Pro Forma Financials

Cost have been forecast for the first year only

Revenue and Costs are outlined in section ?? of the Business Plan

	Year 1	Year 2	Year 3	Year 4	Year 5
Average Revenue per Test	$69				
Number of Tests	101,000	2,000,000	10,000,000	20,000,000	30,000,000
Revenue	[redacted]				
Costs					
Headcount	[redacted]				
Startup	[redacted]				
Manufacturing	[redacted]				
Total Costs	[redacted]				
Net Profit Margin	[redacted]				
Net Profit	[redacted]				

George McBride

EXHIBIT 2

GMcBride/cardiob at.com

From: George McBride
S nt: Sunday, August 15, 1999 22:30
To: Bob Royce (E-mail); Larry Macdonald (E-mail)
Subject: Two Pricings...

Gentleman,

The project plan has been adjusted to include additional resource for the Application development. The project plan should be frozen for plan generation.

A second plan was created that attempts to reduce costs to a plan containing [redacted] The Infrastructure expens s were also adjusted.

[redacted]

Larry,

The concentration should be on the [redacted] plan.

But, if there is time, the reduced deferred Project Plan "Low Cost [redacted]." and a new column in the Infrastructure tab of the spread sheet can be used to generate a plan that comes in around [redacted] This would be a nice back up to the discussion if the question is asked, "Can you do it for less?". I have a meeting out of the office first thing, 0800 and will be in by 0900.

The spreadsheet and 2 project plans are attached.

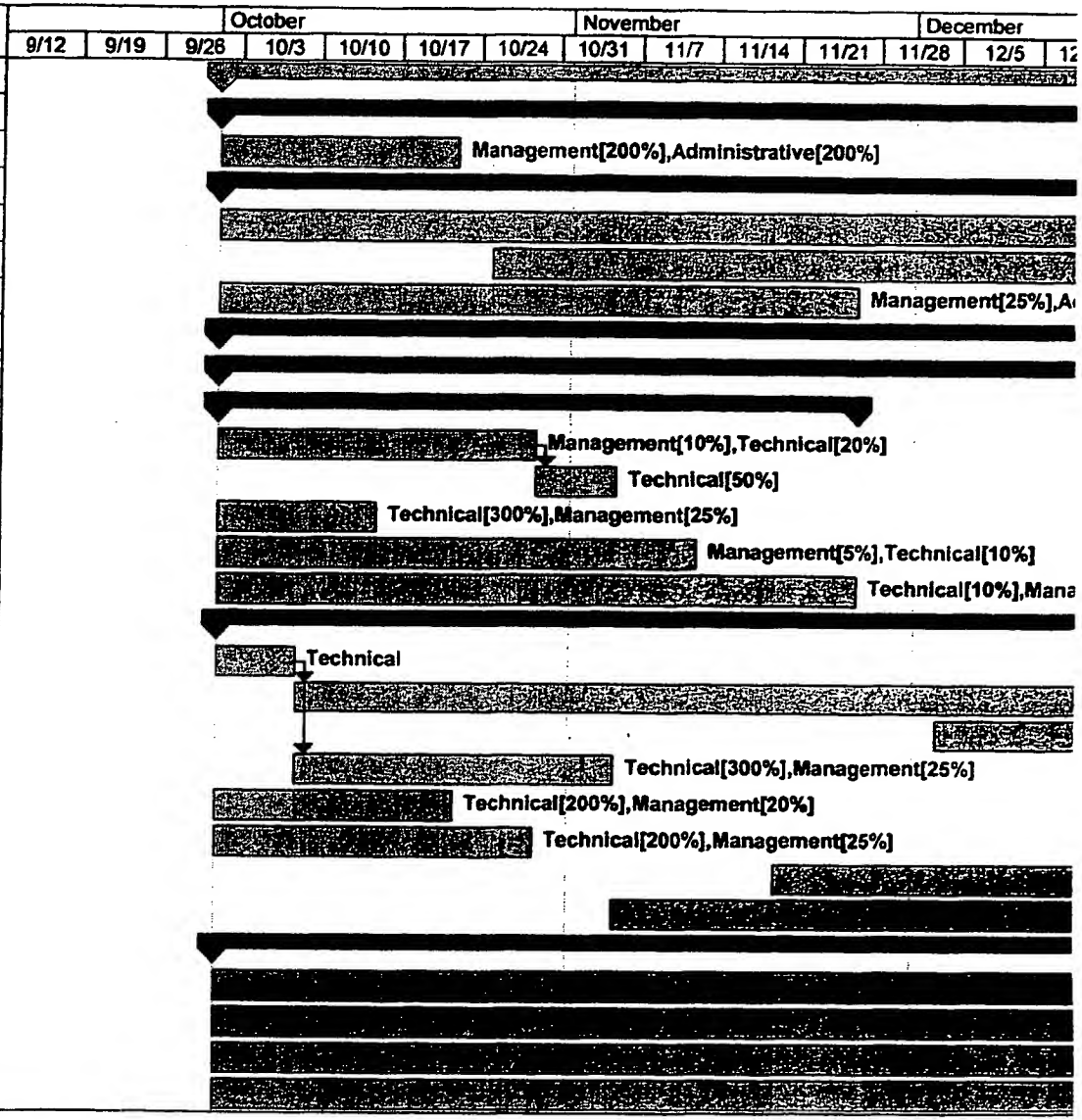
Low Cost - 1-3 Months Project ...

1-3 Months Project Plan.mpp (1...

First Cut Pro Forma.xls (116 K...

Ge rge McBride
Asset Technologies, Inc.
Direct Phone: 602-418-0464
Offic : 480-998-8900
Fax: 480-922-0500
Email: gmcbride@assettech.com
Web Page: www.assettech.com

ID	Task Name
0	**Cardi beat.com Milestones Project Plan Depl yment**
1	**Valuation / Milestone Project Plan - Phase 1**
2	Start Up - Hiring, space, general Organization
3	**Administration**
4	Accounting System
5	Benefits Plan
6	Start recruiting
7	**Deploy Prototype System (25 Patients) (Start+ 3 Months)**
8	**Internet Deployment**
9	**Plant and Equipment**
10	Acquire appropriate hardware and software
11	Implement First Generation Web Servers
12	Create cardiobeat.com Web Page
13	Evaluate and select ISP's
14	Plan for general deployment volumes
15	**The Heart Test Functions**
16	Create Heart Test dB
17	Build Heart Test Download
18	Build Client Data Retrieval
19	Code Test Data Comm tools for user and back
20	Build doctor's office / clinic test procedure
21	Trendline evaluation and Reporting
22	Create Instructional Video Management Facility
23	Perform Heart tests employing Downloaded Ap
24	**Client Administrative Systems**
25	Create Administration dB
26	Build (Admin) Patient set-up
27	Customer Database Maintenance
28	Create client UI

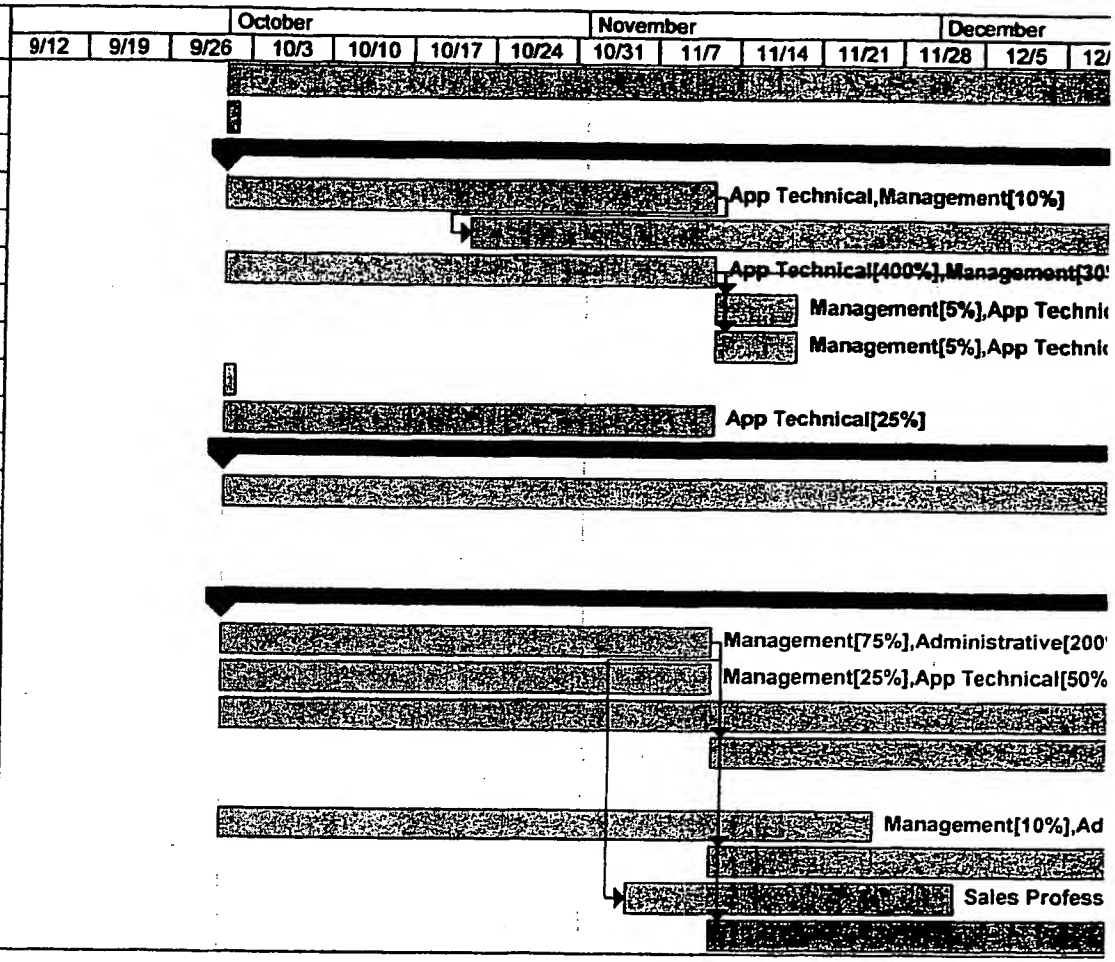


oject: Cardiobeat.com Milestones Project Plan Deploymer
ate: Wed 8/14/02

Task	Rolled Up Task	Project Summary	
Split	Rolled Up Split	External Milestone	
Progress	Rolled Up Milestone	Deadline	
Milestone	Rolled Up Progress		
Summary	External Tasks		

Note: Plan Created 8/15/1999

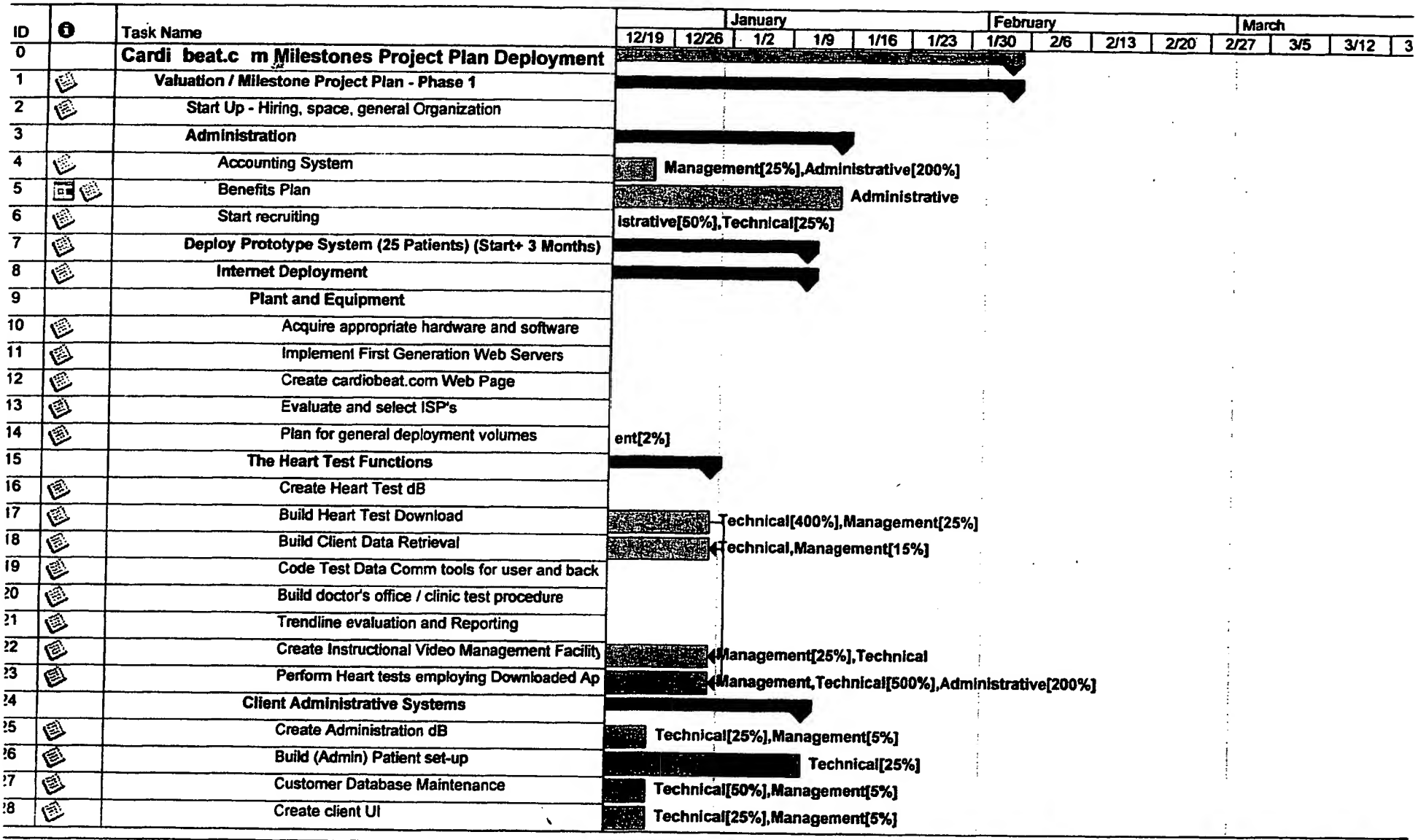
ID	Task Name
29	Install credit card charge facility
30	Create reporting
31	**Application**
32	Design General Distribution Test Interface
33	Build User Interface for test
34	Productize Heart Test Code (v1)
35	Split Code into patient and server applications for initial t
36	Test algorithms for point placement module
37	Code Filters
38	Code User Feedback
39	**Manufacturing**
40	Design first generation sensors
41	Select manufacturer and start volume tests
42	Manufacture First Generation Sensors (50 copies)
43	**Sales and Marketing**
44	Create sales and marketing Plan
45	Submit Patents
46	FDA Approval
47	Create plan for publicity / demand creation
48	Organize test subjects
49	Introduce concept to selected MD's
50	Create Instructional Video
51	Investigate Cardiologist Review of Test Data
52	Alliances / product sharing



oject: Cardiobeat.com Milestones Project Plan Deploymer
ate: Wed 8/14/02

Task	Rolled Up Task	Project Summary	
Split	Rolled Up Split	External Milestone	
Progress	Rolled Up Milestone	Deadline	
Milestone	Rolled Up Progress		
Summary	External Tasks		

M Note: Plan Created 8/15/1999

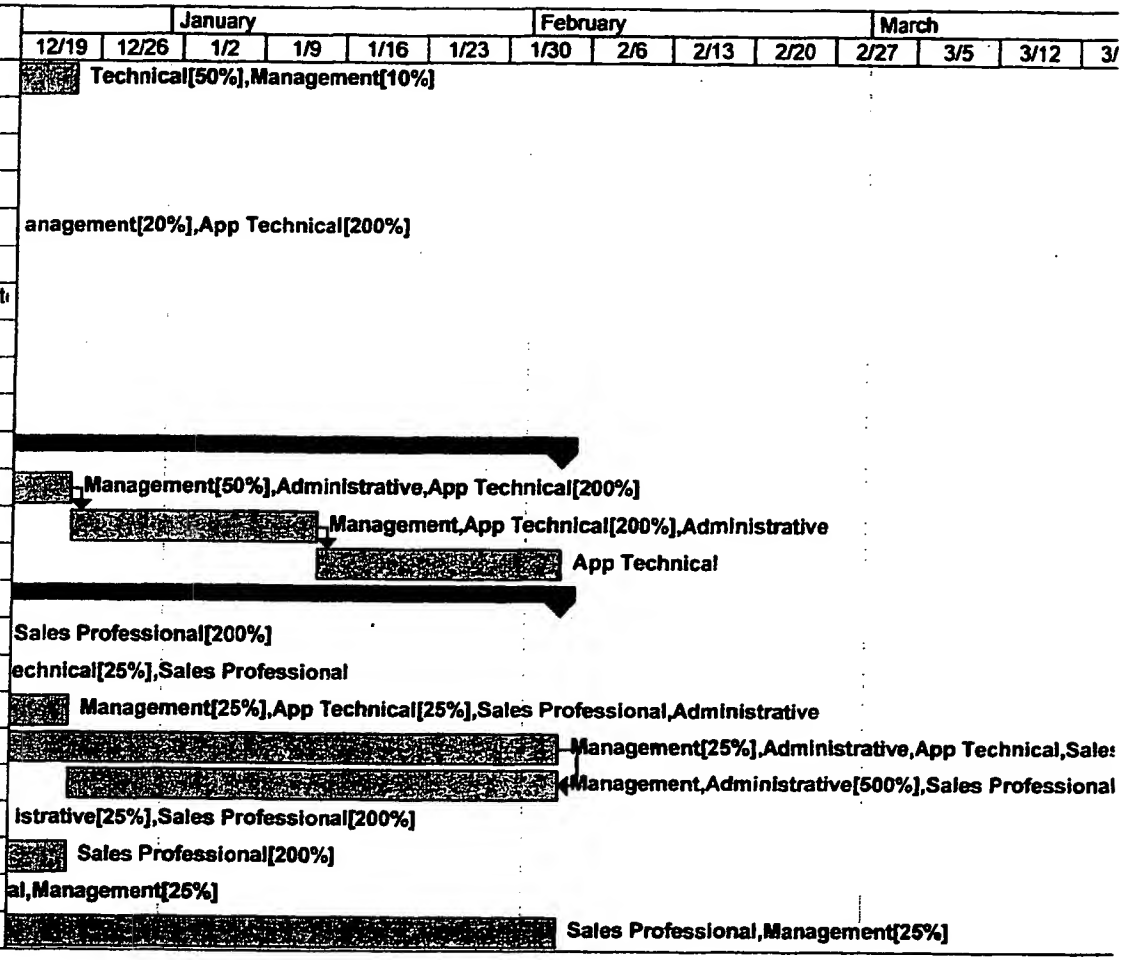


oject: Cardiobeat.com Milestones Project Plan Deploymer
ıte: Wed 8/14/02

Task		Rolled Up Task		Project Summary	
Split		Rolled Up Split		External Milestone	
Progress		Rolled Up Milestone		Deadline	
Milestone		Rolled Up Progress			
Summary		External Tasks			

Note: Plan Created 8/15/1999

ID		Task Name
29		Install credit card charge facility
30		Create reporting
31		**Application**
32		Design General Distribution Test Interface
33		Build User Interface for test
34		Productize Heart Test Code (v1)
35		Split Code into patient and server applications for initial t
36		Test algorithms for point placement module
37		Code Filters
38		Code User Feedback
39		**Manufacturing**
40		Design first generation sensors
41		Select manufacturer and start volume tests
42		Manufacture First Generation Sensors (50 copies)
43		**Sales and Marketing**
44		Create sales and marketing Plan
45		Submit Patents
46		FDA Approval
47		Create plan for publicity / demand creation
48		Organize test subjects
49		Introduce concept to selected MD's
50		Create Instructional Video
51		Investigate Cardiologist Review of Test Data
52		Alliances / product sharing



oject: Cardiobeat.com Milestones Project Plan Deploymer
te: Wed 8/14/02

Task		Rolled Up Task		Project Summary	
Split		Rolled Up Split		External Milestone	
Progress		Rolled Up Milestone		Deadline	
Milestone		Rolled Up Progress			
Summary		External Tasks			

Note: Plan Created 8/15/1999

2 **Start Up - Hiring, space, general Organization**
Work quickly to build work force into a competent force for Internet Deployment

4 **Accounting System**
- utilize Profit
- Get chart of accounts
- set up prelimanary A/P
- Banking relations
- Payroll service

5 **Benefits Plan**
- set up health Insurance
- Stock Options (lawyers)

6 **Start recruiting**
- Set plan for recruiting technical talent
  - identify key technical resources that are required
  - identify recruiting agencies to help locate candidates
  - Set salary guidelines
  - Start interviewing

7 **Deploy Prototype System (25 Patients) (Start+ 3 Months)**
Complete an end to end test
- demonstrate download, test operation, upload
- utilize the best sensors that can be produced in 2 months
- Run tests on at least 20 patients
- Produce plan for getting to production quality by start + 6 months

8 **Internet Depl yment**
Fast start will employ ATI facilities to perform these tasks.
ATI possesses the infrastructure to begin work immediately

0 **Acquire appropriate hardware and software**
Utilize the ATI Infrastructure to establish an operating environment
- Oracle / Application Server
- Cardiobeat.com web page
- Messaging Capability

Configure a first generation server for performing the test
- Set up with Oracle and utilize for Testing and Production
- This machine should be capable of handling at least 100,000 tests per month.
- Would include DASD to hold 5 million tests.

1 **Implement First Generation Web Servers**
For the new box -
- Install Unix
- Install Oracle with OAS
- Install all other development tools

2 **Create cardiobeat.c m Web Page**
Design and code Cardiobeat.com home web page
- Company Introduction
- Application for test patient
- Job opportunities

3 **Evaluate and select ISP's**
Find backup computing resorces for supporting high volumes that cannot be handled internally.

14 **Plan for general deployment volumes**
Planning for volumen production and testing to the extent possible.

16 **Create Heart Test dB**
This database holds the test data for each client
Archiving will be considered in the second phase
Design objective for first base should be 1,000,000 tests
Collaborate with the application code team for the database design

17 **Build Heart Test Download**
Key Task -
- Define tools for storing and delivering Application Code to Desk Top
- Version Control
- Tracking "open" customers
- Web Pages to guide customer through download
- "On Client" Application version detection and management
- Customer profile update
- Design the Client side Q&A

18 **Build Client Data Retrieval**
Code and Client interface to retrieve and deliver archived tests and trend line calculations.

19 **Code Test Data Comm tools for user and back room**
Tools for routing tests and other patient information to doctors and hospitals
- Client side design to collect name and routing information
- Form to order routing
- Confirmation of routing
- Emergency Procedures for out-of-line conditions

20 **Build doctor's office / clinic test procedure**
Create logic to take tests, deliver to the doctor for immediate evaluation
Characterize differently form individual Customer tests in amount and sophisitcation of the data.

21 **Trendline valuation and Reporting**
Multiple tests can be scrutinized for trends in cardiovascular performance
- define trend analysis requirements
- build test code
- define initial graphical presentations

22 **Create Instructional Video Management Facility**
Video to instruct and demonstrate proper sensor attachment and other procedures to the customer.

23 **Perform Heart tests employing Downloaded App Code**
Organize Patients (25)
Get test equipment installed on several test PC's
download code over the web
run the tests
Observe / change procedure

25 **Create Administration dB**
Start work on the Admin DB with resources that can be freed from the main effort.

26 **Build (Admin) Patient set-up**
Procedures for enrolling and tracking each customer
Do the design work necessary to develop the data base and code logic to prepare for a push on these apps in the next phase.

27 **Customer Database Maintenance**
Transactions to
- create accounts
- maintain tests purchased inventory
- communicate account status to the customer
- monitor account status internally

49 Introduce concept to selected MD's
Part market research and part sales to the doctors -
assess receptivity
educate
develop sales strategy based upon experience

50 Create Instructi nal Video
collaborate with the distribution group on the instructional video

51 Investigate Cardiologist Review of Test Data
Compile a coherent testimonial from individuals of stature in the Medical Profession.

52 Alliances / product sharing
Identify support facilities like video players

- determine the requirements
- identify suppliers
- negotiate and close

EXHIBIT 3

GMcBride/cardi b at.c m

Fr m: SoftQue [royce@softque.com]
Sent: Monday, August 23, 1999 10:03
To: George McBride
Subject: FW:

George I thought you might want to see this. rlr -----Original Message-----
From: Warren Williamson [mailto:warren@wlwill.com]
Sent: Tuesday, August 17, 1999 1:45 PM
To: royce@Softque.com
Subj ct:

Bob:
Following are my thoughts and observations about the next generation Thorasic Impedance Measurem nt System: The present Thorasic Impedance Measurement System design can be reduced greatly in size, cost, and power consumption by incorporating newer microprocessor technology which is now available. In particular, Digital Signal Processing (DSP) techniques can be used to perform the filtering and other signal proc ssing functions which are implemented in the current design as individual amplifier and filter circuits. There are numerous DSP processors available now which are capable of performing these functions. In addition, performance will be improved with the use of these techniques. Much of the size and cost of the present design relates to the connectors, switches, display, and other interface components. There is plenty of opportunity for reduction in these areas. Another step which can be taken if necessary to futher reduce size is to use Surface Mount Technology. Even if not necessary for size reduction, it may be the best choice as this is a more modern assembly method and is becoming very widespread. The first step in the redesign process is to review the available microprocessor and DSP technology and select the appropriate proc ssor based on cost, power consumption, external components required, and other design consideratons. W also need to carefully specify the product functionality with the features necessary for the way we intend to apply it. Then we can do the circuit and firmware design and produce circuit boards and prototypes. I'm looking forward to working with you again on this project. Warren

EXHIBIT 4

Answers to questions regarding Impedance Cardiography

Acceptance:

Impedance has not been widely accepted because its biophysics is not well investigated and the factors involved in the production of the signal are multiple and poorly understood. Impedance began to be promising about the same time that cardiac ultrasound came onto the scene. The physics of sonar was well researched; the technology proliferated rapidly and was marketed by many startup companies in the private sector. Virtually all of the research on impedance cardiography was done for the Apollo space flight by a team of researchers under Dr. William Kubicek, a physiologist at the University of Minnesota. The University held the patents on the device as the Minnesota Impedance Cardiograph. Like most universities, it was a disinterested entrepreneur, absent motivation from extensive clinical testing the technology languished. Computer power had to increase sufficiently to detect and assemble the average by separating the wandering "dirty" signal from cardiac impedance. Until the computing power was available, impedance would be seriously handicapped when comparing values against the "gold standard" for measuring cardiac output - measure the average of multiple cardiac cycles collected over a period of multiple seconds to minutes. Because it's accuracy was in question, and all of the gold standards for measuring cardiac output were invasive and thus not applicable to day to day monitoring any place but the intensive care unit, there was no precedent for it's use in the outpatient clinic setting .The medical community is conservative in embracing new ideas especially those not completely understood and explained by "hard " science facts and principles. Of course the electrocardiogram is still not completely explained and understood by hard science biophysics, but its utility has been accepted and validated through extensive clinical correlation and research, and even now new insights are gained annually about the electrocardiogram.

Except for a few of us, there is little clinical experience with this technology and therefore the opportunity for, and participation in, experience with the technology must occur before widespread acceptance can follow.

This is where a research partnership with a few large hospitals could be helpful. To validate the technology requires correlation with invasive measurements and one large group that almost always gets monitored early post operatively are coronary bypass patients and heart surgery patients in general. Invasive monitoring lines are removed as early as possible to reduce the risk of infection, but if a noninvasive technique can be shown to be reasonably accurate, safe and cheaper than the invasive one, every hospital administrator in the country providing cardiac surgery and cardiac care services will want to pursue the more cost effective strategy. Considering the substantial costs of invasive monitoring and the affordable cost of impedance, the technique could be extended to cardiac rehabilitation and out patient heart failure monitoring and management. Congestive heart failure (CHF) is the most costly DRG for Medicare and is projected to expand almost exponentially in our aging population over the next 3 decades. The opportunity to substantially reduce the number of costly hospitalizations in the ever growing heart failure population and its economic impact on business government and society cannot be under estimated. I firmly believe that CHF is so much better treated with outpatient impedance directed therapy than with the typical inpatient course of care that only under extreme conditions such as sepsis or malignant arrhythmias should a patient with CHF be admitted to hospital. CHF is not a disease requiring hospitalization for it's optimum management. The disease must be managed in

the day to day environment where the patient lives. The strict diet, activity, and fluid restriction of the hospital environment only works until the patient leaves to go home, but is not applicable once he gets home, so he gets into trouble a little later and back he comes for another round of expensive care in the "ivory tower". Accurate, scheduled, hemo-dynamic surveillance can detect impending deterioration and direct appropriate treatment before the patient's condition reaches crisis proportions.

2) Demand and pricing:
The formula you used is right. If its' accuracy is valid then it's utility should be able to be proven. If it is perceived to have utility, widespread usage is inversely proportional to price.

What we are considering is a new paradigm for "medical technology business" where the profit has traditionally been made from selling the machine or "hardware". The new model is service or software analogous in that the machinery is viewed as a linkage device decreasing in purchase price all the time while ISP's underwrite the hardware purchase to get consumers tied to long-term service agreements. Digital satellite dishes, cell phones, digital pagers, and essentially all new age machinery are useless without service providers. Hell, even your car has OBD so you can't tune it without special software in the hands of a select few service providers.

Jim Buell 9-18-99

EXHIBIT 5

New Product
BUSINESS PLAN
FOR
cardiobeat.com

to deliver

"HEART TRACK"

an Internet based heart performance procedure for physicians and patients

17350 North Hartford Drive
Scottsdale, AZ 85255
480-419-3956
email: plan@cardiobeat.com

Presented to:

10/1/1999

Copy ____ of ____ copies distributed

This business plan contains information that is not to be shared, copied, disclosed or otherwise compromised without the consent of cardiobeat.com.

Cardiobeat.com Business Plan
Table Of Contents

Executive Summary *1*

Cardiobeat.com Plan 1
Mission Statement 2
"HEART TRACK" is a "Sea Change" in the Management of Cardiovascular Health 2
Unique Features 3
Marketing Objectives 4
Initial Phase Accomplishments 5
Capital Required for Start-up and Three Months Operation 8

The Business *8*

The Initial Plan 8
Description of the Business 8
History of the Business 8
Founder of the Business 9
"HEART TRACK" Acceptance 9
Management & Operations 10
Regulations & Licensing 11
Objectives 12

Marketing *13*

Market Research 13
Target Markets 13
Competition 16
Objectives 17
Unique Selling Benefits 18
Channels of Distribution 18

The Products *21*

Deployment Tools ..... Error! Bookmark not defined. 19
Test Logic ..... Error! Bookmark not defined. 19
Customer Management ..... Error! Bookmark not defined. 19
Sensor Manufacturing and Distribution 19

Risks *22*

Deleted: 3
Inserted: 3
Deleted: 2
Deleted: 4
Inserted: 4
Deleted: 3
Deleted: 5
Inserted: 5
Deleted: 4
Deleted: 13
Deleted: 13
Deleted: 16
Deleted: 17
Deleted: 18
Deleted: 18
Deleted: 19
Deleted: 19
Deleted: 19
Deleted: 19
Deleted: 20

Description of Risks ..... Deleted: 20
Contingency Plans ..... Deleted: 21
Deleted: 22

Finances 24

Assumptions ..... Deleted: 22
Sources and Uses of Capital ..... Deleted: 22
Income Statement ..... Deleted: 22
Cash Flow Statement ..... Deleted: 22
Deleted: 23

Conclusion 27

Justification for Investment ..... Deleted: 23
Milestones/Implementation Timetable ..... Deleted: 23
Deleted: 24

Appendix 35

Resumes ..... Deleted: 24

Executive Summary

Cardiob at.com Plan

Cardiobeat.com (Cardiobeat) has developed a software product, "HEART TRACK", which will revolutionize heart health care and heart disease treatment throughout the world. The information collected dramatically improves cardiovascular health assessment. The relatively low price and "on demand" availability at homes, physician's offices, and hospitals will encourage increased usage. A database of tests taken periodically will support health management through trend analysis. The cumulative effect of regular testing, precise measurements, and computer analysis, will be improved cardiovascular health at greatly reduced costs.

Fifty eight million Americans suffer from heart disease and five million Americans are victims of heart failure. Heart disease is the most prolific killer and the most expensive area of medical treatment in America. Extrapolating the US statistics to the industrial world populations, creates projections of 230 million victims of heart diseases and 21 million victims with heart failure. There is a large, motivated, prospect base.

Deleted: s
Deleted: to
Deleted: million

"HEART TRACK" will be delivered over the Internet to patients and physicians. The user will purchase leads and sensors for performing the procedure. The "HEART TRACK" Software will be downloaded on demand for performance of the test with instructions. The user will plug the sensors into the serial port of the client workstation for data collection.

Cardiobeat is seeking $1.5 million in initial capital to validate the commercial potential of "HEART TRACK" through productization of the software procedure and creation of the delivery capability. Deployment of "HEART TRACK" over the Web requires that Cardiobeat complete the following major tasks. These tasks are detailed in the attached project plan:

1. Productize the "HEART TRACK" software for use by novices
2. Build deployment management tools "HEART TRACK and a database to store "HEART TRACK" results
3. Execute a sales and marketing plan to create demand for 25,000 tests per month in 7 months and protect the technology
4. Create a capital budget and execution plan for bringing "HEART TRACK" to a mass market product

The first phase of implementation is a three-month plan requiring 35 professionals to complete the tasks. Completion all components of the finished product will position Cardiobeat to begin the commercialization of "HEART TRACK" during the next three months of operation.

Today, lack of timely, precise, information inhibits management of cardiovascular health by patients and physicians. In many cases, the first symptom of heart disease is sudden death. "HEART TRACK" is a non-invasive procedure to augment and supplant the Right Heart Catheterization procedure, as the "gold standard" for diagnosing cardiovascular condition. "HEART TRACK" will be offered over the web for use in the physician's office or at home by the patient.

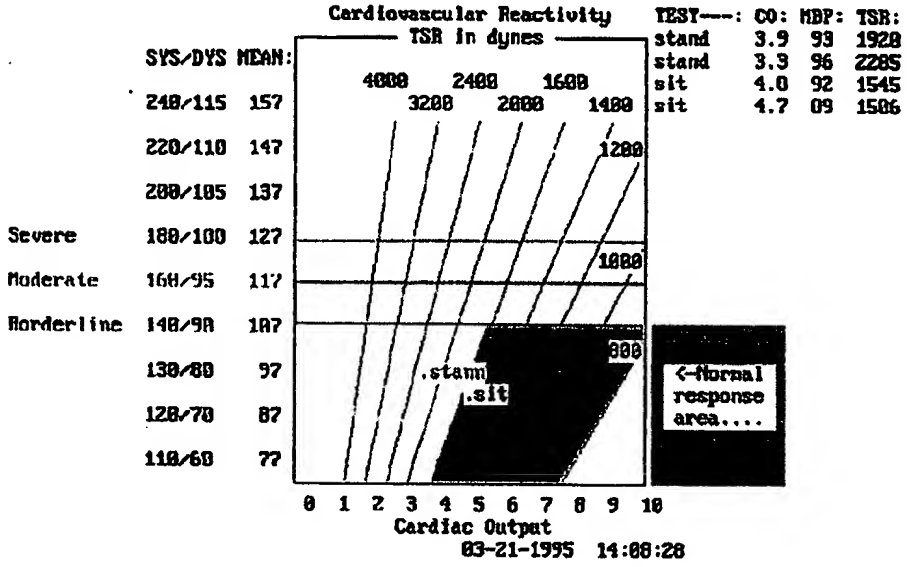
"HEART TRACK" is a sophisticated software tool for collecting, filtering, analyzing, and presenting detailed information about the cardiovascular system. Sensors, attached to the throat, and chest, of

the patient provide the facts necessary for performing the test. The sensors are connected to the Internet through a personal computer's serial port (or Universal Serial Bus).

"HEART TRACK" employs a medical technology called impedance cardiology. An undetectable alternating current is introduced into the body by placing circuit generating electrodes on the forehead and distally on the abdomen. It is possible to measure resistance changes across the thorax. The drop in voltage between sensors is measured and mathematically reduced to produce a profile of the patient's cardio-vascular system, with results equivalent to an invasive heart catherization.

Deleted: .

The following graphic displays an easy to understand representation of three key measurements from the HEART TRACK test.



This chart illustrates the measurement of cardiovascular performance by plotting three variables and highlighting a normal area for a quick understanding of cardiovascular health. The upper right hand corner contains the raw plot data. The Graphic plots along each axis with a separate scale. "CO" is cardiac output in liters (the amount of blood pumped by the heart). "MBP" is the mean blood pressure, an averaging of the two measures (systolic and diastolic). "TSR" is Total Systemic Resistance to blood flow. TSR is a gauge of the resistance in the blood vessels to the flow of blood (clogged artery measurement). Summarization of this data into a single graphic provides a clear assessment of heart health. These variables are three of 19 measurements produced by HEART TRACK.

The measurements are taken 4 times over a 25-heartbeat test period per test. Two tests are sitting and two standing. The act of standing places a substantial strain on the heart. The hearts reaction to this strain is additional information relevant to heart health.

Periodic testing will provide trend analysis that will highlight changes in cardiovascular health. For example, the effect of exercise, weight change, and diet will be reflected in these measurements.

Impedance cardiology was invented in the 30's, employed in the 60's by NASA for the Apollo program, and offered commercially as a clinical instrument in the 80's by the predecessor company to Cardiobeat, Softque, Inc. Cardiobeat has purchased the technology from Softque, Inc.

The revenue potential is substantial, as "Heart Track will, will generate substantial revenues. Fifty million tests per year at a price of $50, a 10% penetration of the market, the revenues are $2.5 billion. Additional capital will be required to reach this market share.

Deleted: T

Deleted: R

Deleted: P

Deleted: : ¶
"HEART TRACK"

Mission Statement

To establish Cardiobeat with physicians, managed care organizations, hospitals, cardiovascular patients and key governmental advisory committees as the premier company at the center of the Internet Health Care revolution

To establish HEART TRACK as the first significant economical and user friendly set of health care services from Cardiobeat that revolutionize the monitoring and treatment of heart disease in patientsjn the U.S. and worldwide

Deleted:

To manage the business of Cardiobeat in such a manner to maximize the ROI to its shareholders

To manage the business of Cardiobeat in a very professional and ethical manner so as to establish a reputation that will attract and retain customers and investors

To establish a follow up program that will enable Cardiobeat to market other non-invasive medical tests services to reinforce their commitment to heart disease and its related effects

"HEART TRACK" is a Paradigm Shift in the Management of Cardiovascular Health

Deleted: p

Deleted: s

The price and availability of "HEART TRACK" will change the way heart disease is managed.

Cardiobeat will deliver a product providing detailed heart health information at a dramatically lower price. Easy access to the test and its information will increase the patient's knowledge and encourage better compliance with treatment regimens. The amount of information for analytical purposes will increase to 100's of millions of data points. This information will create a new statistical base for understanding heart disease.

The record keeping function and its use for computing trends will become a magnet for other health information. Periodic testing amplified by trend analysis will encourage repeat visits. This partnership of health management through time will dispose patients to expand information content. Since the test collection and trend analysis will always be here, why not add medication history, and other medical information. Sharing with physicians is an added incentive.

EXHIBIT 6

DEMO - Message (Rich Text)

File Edit View Insert Format Tools Actions Help

Reply Reply to All Forward

Arial 10 B I U

This message contains formatting that is best viewed with Microsoft Word. Click here to display in Word.
You forwarded this message on 10/18/1999 08:09. Click here to find all related messages.

From: SoftQue Inc. [royce@softque.com]
To: George McBride; Larry K. Macdonald
Cc:
Subject: DEMO

Sent: Sat 10/16/1999 17:47

CBI

CardioBeat.com
Engineering Department
3427 East Huber - Mesa, AZ - USA
www.cardiobeat.com
Email - royce@cardiobeat.com
Ce. 602/534-7421
Fax 480/832-6300

10/16/99 6:20:38 PM

Status of 2nd generation Portable Cardiac Lab (PCL)

George I guess that you have been using this PCL software as a basis and renaming it as "Cardiac Track" software.

Choices:

1. Assuming that we do NOT produce an interim product for a DEMO:

3rd generation CardiacTrack software:
I on the other hand have always believed that if we ever got funding we would start over with Client and Server software designed around the basic research and math that both Dr. Buell and I have worked in the original DOS based version know as the Cardiac Performance Lab (CPL). This would insure the most efficient use of the very small amount of time allocated to develop this product. This is a major change and it will require a complete rewrite to produce an efficient product that is small in size and easy to download over the net.

People Required:
With a couple of quality programmers and at least one and possible two high quality engineers to work me in my division of the company, then I believe that we can produce this product in a timely manner.

I would have the job of **coordinating** four major efforts:

1. A patient hardware/interface device with four lead electrode assembly
2. Client software. (User)
3. Server software (Database & intelligent reports)

DEMO - Message (Rich Text)

File Edit View Insert Format Tools Actions Help

Reply Reply to All Forward

This message contains formatting that is best viewed with Microsoft Word. Click here to display in Word.
You forwarded this message on 10/18/1999 08:09. Click here to find all related messages.

From: SoftQue Inc. (joyce@softque.com)
To: George McBride; Larry K. Macdonald
Cc:
Subject: DEMO

Sent: Sat 10/15/1999 17:47

4. Working with the WEB developers on specifications. Making sure everyone is on the same page using the same specifications. These specifications will be somewhat liquid and will change as required. The engineers/programmers will want some things and the Visual Basic programmers on both the Client and Server products will want their ideas incorporated as well as the WEB designers/programmers.

The server product would be the most complex product and would require a great deal of coordination between the Visual Basic programmers and the WEB programmers.

With my knowledge of the overall product and the creative input of the programmers and engineers we should end up with a very high quality product.

2. Assuming that we DO produce an interim product for a DEMO:

2nd generation Portable Cardiac Lab (PCL)
I would continue to develop the PCL software and make it work and act somewhat like the CradiacTrack product.

If I do NOT sell my company in a timely manner I will need a least one programmer to work with me on a full time basis. I would want this individual to be a full time employee. We would need funding of some kind if this is the case.

The attached flowchart assumes that we use the interim product. All most all of this work would have to be repeated when we start designing the CardiacTrack product. Of course some of it could be used but not much.

I am NOT in favor of this manner of time management. I realize it may help to sell the product and it may have to be done.

Developing the PCL software could also backfire on us, as the device a will not look or feel like the actual product. If you show a physician a "Stand Alone System" and then tell him your going to split it up he may not understand the concept. Or he may not want to.

I believe that producing a PCL demo will cause MAJOR problems but if you *all* insist that it be done then lets get a bit of funding and do it.

I need feedback on this - is this what you need for Tuesday?

overview.jpg (64 KB)

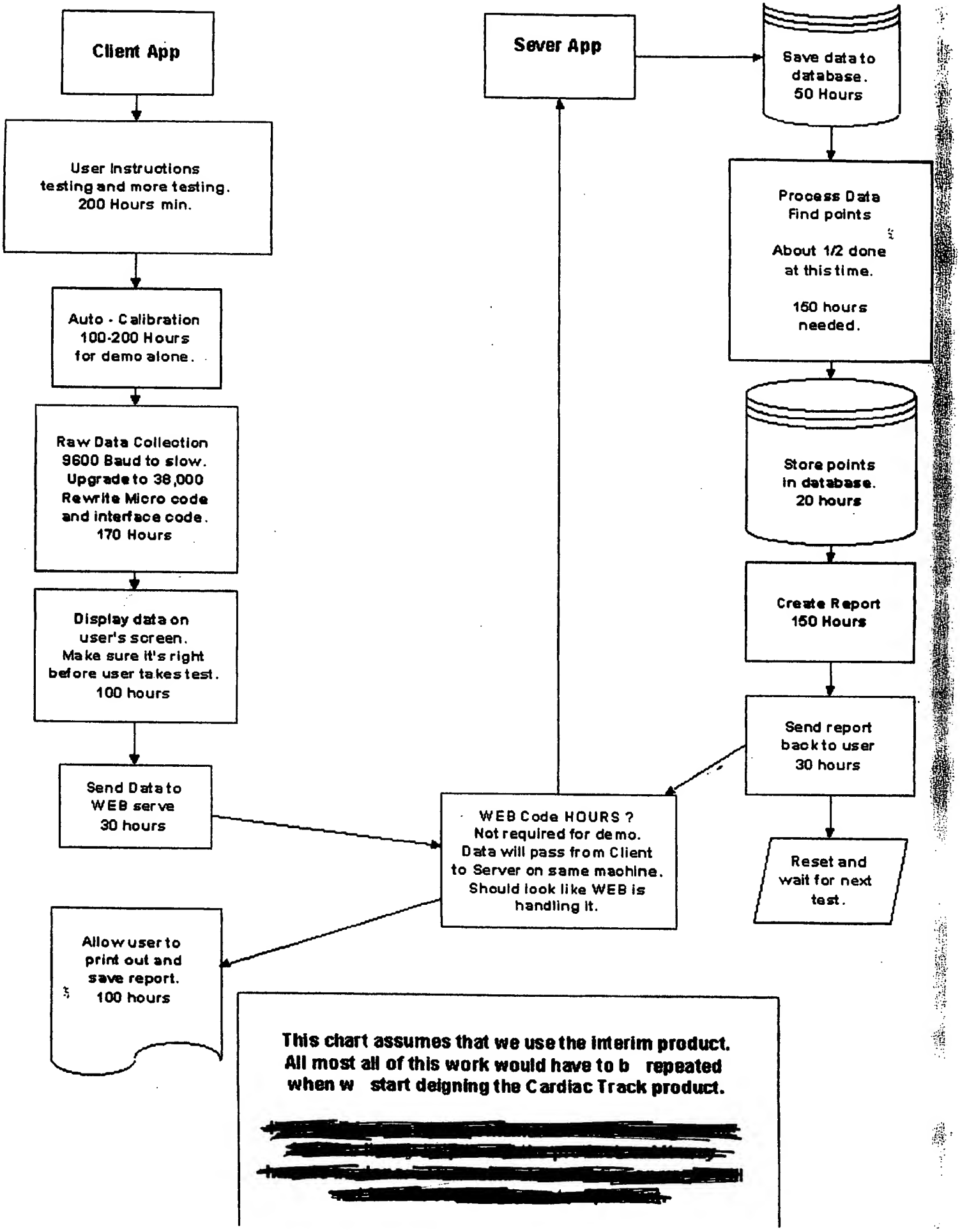

Client App
User Instructions
testing and more testing.
200 Hours min.
Auto - Calibration
100-200 Hours
for demo alone.
Raw Data Collection
9600 Baud to slow.
Upgrade to 38,000
Rewrite Micro code
and interface code.
170 Hours
Display data on
user's screen.
Make sure it's right
before user takes test.
100 hours
Send Data to
WEB serve
30 hours
Allow user to
print out and
save report.
100 hours
Sever App
Save data to
database.
50 Hours
Process Data
Find points
About 1/2 done
at this time.
160 hours
needed.
Store points
in database.
20 hours
Create Report
150 Hours
Send report
back to user
30 hours
Reset and
wait for next
test.
WEB Code HOURS ?
Not required for demo.
Data will pass from Client
to Server on same machine.
Should look like WEB is
handling it.
This chart assumes that we use the interim product.
All most all of this work would have to b repeated
when w start deigning the Cardiac Track product.

EXHIBIT 7

Cardiobeat.com
a paradigm shift in cardiovascular health

George McBride
gmcbride@cardiobeat.com
(480) 419-3957
17350 North Hartford Drive
Scottsdale, AZ 86255

December 22, 1999

Overview of software development status for the CARDIO-TRACK phase one product deliverable

- **Server CARDIO-TRACK data reduction and analysis module code**
- **WEB data transfer application**
- **Client application**
  - User friendly tools
    - Help
    - AVI Videos (Sent with startup CD)
    - Checks for misplaced sensors
    - Checks for correct waveforms
    - Click once to start test
    - Press space bar or mouse to halt or suspend test
  - Automatic Transmission from the host server to client
    - Update Client application software (real time)
    - Data movement
  - Transmission to the host server from the client
    - Data movement
- Server processing
  - Processes data
  - Create reports
  - Routing to client & physicians
    - E-Mail Reports
    - Emergency calls
- Database
  - Storage of Client data
- Communications between parties (patient and physician)
- Customer service module

Patrick Smith – Data Base Administration

- The Oracle decision - what are the alternatives and why Oracle
- Scalability
- Web Interface capabilities
- Hardware Options

Brett Scott – Microsoft Visual Basic / Web Coding

- The Microsoft environment
- Moving protected Data
- The User Interface

Bob Gubser – Sensor Manufacturing

- Describe PRA
- Review Cardiobeat memo on sensor engineering and manufacturing
- Discuss early steps to produce prototype

a paradigm shift in cardiovascular health

George McBride
gmcbride@cardiobeat.com
(480) 419-3957
17350 North Hartford Drive
Scottsdale, AZ 86255

Cardiobeat.com Software Status Review 22 December 1999

Bob Royce

- Overview of software environment
  - CARDIO-TRACK test
  - User friendly tools
    - Help
    - Videos
    - Checks for misplaced sensors
  - Transmission from the host server to client
    - Application software
    - Data movement
  - Transmission to the host server from the client
    - Data movement
    - Routing to physicians
  - Server processing
  - Database
  - Communications between parties (patient and physician)
  - Customer service module
- CARDIO-TRACK test code
  - Calculations
  - Reporting
  - Data transfers

Patrick Smith – Data Base Administration

- The Oracle decision - what are the alternatives and why Oracle
- Scalability
- Web Interface capabilities
- Hardware Options

Brett Scott – Microsoft / Web Coding

- The Microsoft environment
- Moving protected Data
- The User Interface

Bob Gubser – Sensor Manufacturing

- Describe PRA
- Review Cardiobeat memo on sensor engineering and manufacturing
- Discuss early steps to produce prototype
- Characterize the prototype

Items for the future

- Help Support
- "Use" Video's
- Customer Support Modules
- Volume test storage subsystem

George McBride
gmcbride@cardiobeat.com
(480) 419-3957
17350 North Hartford Drive
Scottsdale, AZ 86255

Characterize the prototype

Items for the future

Help Support
"Use" Video's
Customer Support Modules
Volume test storage subsystem